REMARKS

I. PRELIMINARY REMARKS

Applicants submit herewith a Request for Continued Examination.

Claims 1, 3-7, 9-33, 35, 42-44, 46-66, 74-77, 82-88, and 91-97 are pending in the application. No claim amendments are presented at this time.

II. APPLICANTS' INVENTION

The present invention relates to a porous polytetrafluoroethylene tube covered by one or more layers of porous polytetrafluoroethylene film, wherein the film-covered tube circumferentially distends from a first circumference upon the application of a circumferentially distending force such as applied by an internal pressure. The film-covered tube exhibits minimal recoil following the removal of the circumferentially distending force. The porous polytetrafluoroethylene film-covered tube has a second circumference that is at least 100% larger than the first circumference (the second circumference achieved by circumferential distension by force) which remains substantially unchanged by further increasing force. The porous polytetrafluoroethylene film-covered tube itself provides the circumferential distensibility up to the limit, without need of additional plastically deformable components such as metal stents. It is useful as a liner for pipes and vessels, particularly those having irregular luminal surfaces to which the polymeric tube can smoothly conform. The inventive film-covered tube is particularly useful as a liner for both living and prosthetic blood vessels. The limiting second circumference is of particular value for applications of this type in that it can be used to prevent further undesirable dilatation of the blood vessel into which it is fitted.

III. REJECTION OF CLAIMS 1, 3-7, 9-17, 19-31, 33-35, 42-44, 46-66, 74-77, 82-88, AND 91-97 UNDER 35 USC 102(e) OVER SHANNON et al.

Shannon et al. teach a method of making an ePTFE tube having a helically applied reinforcing film radially enlargeable by the subsequent application of internal pressure. The method of making this composite tube is stepwise, requiring that a tape-reinforced ePTFE tube is fitted over a mandrel of slightly smaller diameter than the inside diameter of the reinforced ePTFE tube with the tube ends temporarily secured to the mandrel, and subjected to a temperature of

about 355 °C for 10 minutes. According to the example described at col. 6, line 39 to col. 7, line 7, the mandrel is of 0.05 inch smaller diameter than the inside diameter of the reinforced ePTFE tube. The process is repeated 5 times, resulting in shrinkage of the reinforced ePTFE tube from an inside diameter of 0.5 inches to an inside diameter of 0.3 inches. The resulting 0.3 inch inside diameter tube is subsequently radially enlargeable back to its original inside diameter of 0.5 inches, an increase of the inside diameter of about 67%.

At col. 6, lines 39-43, Shannon et al. state that "...it is expected that in most applications the desired radial shrinkage of the graft will be accomplished with the use of no more than five (5) progressively smaller rigid mandrels."

The present claims specify that the radially enlargeable film reinforced ePTFE tube is enlargeable by an increase of circumference (and, likewise diameter) of at least about 100%. There is absolutely no indication in the '373 patent that such is possible by the method taught by Shannon et al. Indeed, the present claims require that, at a minimum, the enlargeability of the reinforced tube is 50% greater than the maximum indicated by Shannon et al.

This difference is because the process described in the present application that results in the present invention is different from anything taught by Shannon et al. The film tube is made at the larger diameter and then shrunk to the smaller diameter over the ePTFE substrate tube (i.e., a longitudinally extruded and expanded (stretched) tube) by the application of tension to the opposing ends of the film tube after it has been fitted over the smaller diameter substrate tube mechanically shrinks the film tube against the outer surface of the substrate tube. This diametrical shrinkage results in a substantial change in the pitch angle of the hecially-wrapped film and enables the subsequent large diameter increase in the resulting tube when that tube is exposed to adequate internal pressure, and to also provide the 'second circumference' at which this enlargement is halted in spite of further increasing pressure as the pitch angle of the helically-wrapped reinforcing film decreases with the increasing diameter. The processes of Shannon involve the use of applied heat to accomplish any diameter change; nothing is described that would result in a change of pitch angle of the reinforcing film. Again, there is nothing described in Shannon et al. that suggests the amount of diameter increase possible with the present invention.

The Examiner states that "The tube or article [of Shannon et al.] is fully capable of increasing to at least 100% the first circumference since the device is made of the same materials and has the same thickness, it inherently must possess the same physical properties."

It is well understood in engineering and material sciences that simply because two articles are made of the same materials they will have the same properties only if they are processed in

the same way. It is commonplace to process the same materials in different manners to achieve different physical properties. Polymers, metals, chemicals, etc. are processed in many various different ways to achieve different results (e.g., tensile strength, and hoop strength in tubes); there are thousands of patents teaching improved results by altering the processing methods of specific materials. Simply because Shannon et al. used the same materials is absolutely no indication that the results will be the same. The present invention uses a superior process to achieve superior results.

Also in this regard, applicants would point out that there is no suggestion in Shannon et al. as to how a diametrically enlargeable tube (to a limit) might be achieved without the resulting tube having 'recoil,' that is, the tube decreasing in diameter when the force causing the enlargement is removed. To have any value as a vascular prosthetic, this lack of recoil is critical. It is clearly of no value to be able to diametrically enlarge such a tube using, for example, a catheter balloon, to cause the tube to contact the luminal surface of the vasculature, if, when the balloon is removed, the tube recoils back to a diameter appreciably smaller than the diameter it had been enlarged to by the balloon. The tubes of the present invention are made by a process including an anti-recoil step (step 9 of the flowchart of Figure 4, described, for example, in Example 1 at page 15, lines 17-22). The tube of Example 1 had a recoil amount of only 5.3% (page 16, lines17-18) while another tube (Example 3) made the same way but without the anti-recoil process of step 9 had a recoil amount of 11.3%. A commercially available Impra® vascular graft tested in Example 3 had a recoil of 15.4%. Shannon et al. do not suggest any such additional heat treating process resembling step 9. Claims 10-13, 26, 42-44, 46-66, 74-77, 82-85 and 92-94 include recoil limitations not taught or suggested by Shannon et al.

It is worth noting that the tubes of Example 1 and 3 are of the very same materials. The tube of Example 1, subjected to an additional heat treatment process, had very different physical properties, with recoil of less than half of the tube of Example 3. This is clearly indicative of the fact that two tubes can be made similarly of the very same materials, and yet offer different properties.

Claims 23, 48, 54, 60, 66, and 86-97 specify that the tube is diametrically enlarged by blood pressure. There is nothing in Shannon et al. to suggest tubes enlargeable by blood pressure. The only specific source of an enlarging force taught by Shannon et al. is a catheter balloon; see Figure 3 and col. 10, lines 25-33. It is well known that catheter balloons operate at pressures appreciably higher than the typical maximum of about 150mmHg (3psi) of blood pressure.

Given these differences, Shannon et al. do not anticipate the present invention.

IV. REJECTION OF CLAIMS 86-88, 91 AND 95-97 UNDER 35 USC 102(e) GOLDFARB, US 6,436,135.

Goldfarb teaches a conventional ePTFE longitudinally extruded and expanded tube for use as a vascular graft. The manufacture of these tubes has been known and accomplished for many years. The Impra® vascular graft tested for recoil in Example 3 of the present invention is a graft made by the process taught by Goldfarb. This same process is described by Shannon et al. in the first horizontal line of their flow chart of Figure 1 of the '373 patent and in their specification at col. 3, line 46 to col 4, line 26.

The Examiner asserts that "the claimed physical properties (in this case, recoil) are present in the prior art material to some extent even though they are not explicitly recited."

The present invention begins with such a conventional longitudinally extruded and expanded ePTFE tube (e.g., Example 1 at page 13, lines30-31). This tube subsequently undergoes a number of additional processing steps, particularly step 9 of the flowchart of Figure 4 and described further in Example 1 at page 15, lines 17-22 to provide a radially enlargeable tube that does not have the recoil, after removal of the enlarging force, of a conventional ePTFE tube.

To be clear, while these conventional ePTFE tubes such as those of Goldfarb are known to recoil following the removal of a radially enlarging force. Recoil is the diametrical or circumferential shrinkage of an ePTFE tube following removal of a racially enlarging force. It is described in the present specification at page 7, line 28 to page 8, line 27. Note the Impra® graft measured in Example 3 (as indicative of the prior art) for recoil, having recoil in an amount of 15.4%. Tubes of the prior art, as apparently asserted by the Examiner, do indeed recoil, as clearly demonstrated by Example 3 and the large amount of recoil inherent in the Impra® vascular graft measured in that example (the clear commercially available equivalent of Goldfarb).

The applicants claims are directed to ***LACK OF RECOIL***.

The present invention begins with such a conventional longitudinally extruded and expanded ePTFE tube (e.g., Example 1 at page 13, lines30-31). This tube subsequently undergoes a number of additional processing steps, particularly step 9 of the flowchart of Figure 4 and described further in Example 1 at page 15, lines 17-22 to provide a radially enlargeable tube that does not have the recoil, after removal of the enlarging force, of a conventional ePTFE tube.

The Examiner notes again that "Since the graft is made of the same materials and has the same thickness, it must inherently possess the same properties." As described by Example 1, and the counter example of Example 3, made of the same materials as Example 1 but not treated to substantially reduce recoil, the Examiner's statement regarding 'made from the same materials' is incorrect. It is very clear that the method of processing is critical. The additional method step (step 9 of Figure 4) results in the substantially reduced recoil. This is not taught or suggested in any way by Goldfarb.

Goldfarb clearly teaches ePTFE tubes that recoil. As such, Goldfarb, or for that matter, Shannon et al. as noted above, cannot anticipate claims directed to radially enlargeable ePTFE tubes with minimal recoil.

V. REJECTION OF CLAIMS 18 AND 32 VARIOUSLY UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER SHANNON et al. IN VIEW OF HUGHES et al., US 4,728,328.

Hughes teaches a bifurcated graft with 3 ends; claims 18 and 32 relate to 3-ended grafts. These claims are not suggested by the combination of Shannon and Hughes for all of the reasons described above relating to the differences between Shannon et al. and the present invention.

VI. REJECTION OF CLAIMS 92-94 VARIOUSLY UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER GOLDFARB, US 6,436,135.

These claims, among others noted above, relate to minimal recoil. Again, the tubes of Goldfarb have considerable recoil as indicated by the 15.4% recoil of the Impra® graft tested in Example 3 of the present specification (page 18, lines 1-7). The Examiner acknowledges that the claims are directed to ***lack*** of recoil (resulting from step 9 of the process of the flowchart of Figure 4 of the present invention). He states further, however, that it would be an obvious design modification to modify the minimum recoil. This conclusion is unclear to the applicants because the cited references are entirely silent and apparently unaware of the phenomena of recoil, and make absolutely no suggestion as to any additional process step that would be appropriate to minimize recoil.

The Examiner also states that applicants fail to disclose that minimal recoil solves any problem. The rejection is noted to be under 35 USC 103(a) rather than 35 USC 101; the claimed minimal recoil is clearly not suggested by any of the cited references. That aside, the utility is spelled out at page 7, lines 28-32, where it is noted that previously available porous PTFE tubes recoiled following radial enlargement and consequently required the presence of a mechanical

support such as a stent to hold them in place against the interior surface of a blood conduit (such as a vein or artery). Any porous PTFE tube that recoiled following radial enlargement against the interior surface of a blood conduit would, as noted by the specification, be of little use without the additional support of a device such as a metal stent. The lack of recoil in tubes of this type is clearly of real utility.

CONCLUSION

The Applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance. If there remain any issues that might benefit from further discussion, the Examiner is requested to telephone the undersigned practitioner; likewise, the Applicants request an interview if such issues may remain.

Respectfully submitted,

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